K071402

Special 510k Submission
X3C 1600 Plus Digital Radiographic System

510k Summary

JUN - 8 2007

1. **Submitter:** Imaging Dynamics Company Ltd
Suite 151, Pegasus Way NE
Calgary, AB,
Canada T2E 8M5

Contact person: Shirantha Samarappuli
Manager – Regulatory Affairs
Tel: 403 251 9939; Fax: 403 251 1771

Date Prepared: May 14, 2007

2. **Device Name:** X3C 1600 Plus Digital Radiographic System,

3. **Device Classification:** Class II, 892.1680 (KPR), 892.1630 (MQB),

4. **Predicate Device:** Xplorer 1600 Plus Digital Radiographic System (K062586)

5. **Device Description:** The X3C 1600 Plus is a modification to Xplorer 1600 Plus where the Xplorer 1000 digital radiographic detector (a previously marketed device covered by 510k K992955) in Xplorer 1600 Plus system is replaced with X3C digital radiographic detector, previously marketed device under K070079. The X3C 1600 Plus system is manufactured by Imaging Dynamics.

6. **Indications for Use:** The X3C 1600 PLUS is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. The X3C 1600 Plus (510k submission device) is not intended for mammography.

7. **Comparison with predicate device:** The X3C 1600 PLUS is substantially equivalent to the currently marketed Xplorer 1600 Plus. X3C 1600 Plus device does not alter the fundamental scientific technology from Xplorer 1600 Plus predicate device. The replacement of Xplorer 100 digital radiographic detector (K992955) with X3C digital radiographic detector (K070079) is the only significant change between the 2 devices. X3C 1600 Plus has the same intended use as the predicate device.

    a. Non-clinical tests: The device has been evaluated for performance, biocompatibility and effectiveness as well as thermal, electrical and mechanical safety and has been found to substantially equivalent to predicate device. The design and development process of the manufacturer conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.
    b. Clinical tests: No clinical tests conducted.
    c. Conclusion: The device was evaluated against the predicate device (Xplorer 1600 Plus – K062586) for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Shirantha Samarappuli
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AUG - 9 2013

Re: K071402
Trade/Device Name: X3C 1600 Plus Digital Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: May 18, 2007
Received: May 21, 2007

Dear Ms. Samarappuli:

This letter corrects our substantially equivalent letter of June 8, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1.1 Indications for Use

The U.S. Food and Drug Administration (FDA) requires the following statement to appear in this manual:

"The 1600 Plus is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts but not mammography. Applications can be performed with patient sitting, standing, or lying in the prone or supine positions."

FDA 510(k) for the X4C 1600 Plus: K062586

FDA 510(k) for the X3C 1600 Plus: *to be assigned by FDA*

FDA 510(k) for the X3C Detector Head: K070079

- The 1600 Plus digital radiography system is not to be used for mammography.
- The 1600 Plus digital radiography system should only be operated in conjunction with specified medical x-ray equipment and by trained and licensed personnel.

WARNING! Only certified and properly trained, authorized personnel should be permitted to take x-ray exposures. No practical design can incorporate complete protection for personnel who do not follow proper safety precautions.

WARNING! The appropriate x-ray imaging exposure parameters should be consistent with established Federal and Provincial/State radiation protection practices and medical imaging standards in your institution.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071402